

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Sean A. McCarthy, Douglas A. Holtzman and Andrew D.J. Goodearl
Application No.: 10/718,332 Group Art Unit: 1646
Filed: November 20, 2003 Examiner: Not assigned
Confirmation No.: 3405
Title: NOVEL GENES ENCODING PROTEINS HAVING PROGNOSTIC,
DIAGNOSTIC, PREVENTIVE, THERAPEUTIC AND OTHER USES

CERTIFICATE OF MAILING OR TRANSMISSION	
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INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
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Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
 - ☒ Copies of the cited references B1-B8, and C1-C21 are enclosed.
 - ☒ Copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) [] under 37 CFR 1.98(a)(3) is satisfied by:
 - ☐ the explanation provided on the attached sheet.
 - ☐ the explanation provided in the Specification.
 - ☐ submission of the enclosed International Search Report.
 - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
 - ☐ the enclosed English language abstract.

[] Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

- [] A copy of each above-cited application, including the current claims, is enclosed, except any application filed on or after June 30, 2003, which has been scanned into the PTO's Image File Wrapper (IFW) system and is available to the examiner.
- [] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

REMARKS

A form PTO-892 that included the citation, "Amino acid database, Accession Number P97857, 1997" was attached to the Office Action dated October 2, 2000 in U.S. Application No. 09/388,279, to which priority under 35 U.S.C. § 120 is claimed. Our file for U.S. Application No. 09/388,279, which was transferred from prior counsel, does not contain a copy of this document.

An NCBI GenPept report for Accession Number P97857 that is dated 2000 is cited on the attached form PTO 1449 as reference C17.

Our review of the records for Accession Number P97857 revealed that the first posting of a sequence under Accession Number P97857 in both NCBI/GenPept and Swiss-Prot/TrEMBL occurred in the year 2000. Provided herewith are documents titled "Sequence Revision History: Revision history for P97857" and "UniProtKB/Swiss-Prot entry P97857", cited on the attached form PTO 1449 as references C20 and C21 respectively, which show that Accession Number P97857 first appeared in both NCBI/GenPept and Swiss-Prot/TrEMBL in 2000. Accordingly, it appears that the publication date in the citation for Accession Number P97857 on the form PTO-892 in U.S. Patent Application No. 09/388,279 is incorrect.


It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- [] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- [] Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- [X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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Concord, MA 01742-9133

Dated:

April 12, 2006

PTO-1449 REPRODUCED

ATTORNEY DOCKET NO.
1855.2058-001APPLICATION NO.
10/718,332INFORMATION DISCLOSURE STATEMENT
IN AN APPLICATIONFIRST NAMED INVENTOR
Sean A. McCarthyFILING DATE
November 20, 2003

April 12, 2006

EXAMINER
Not yet assignedCONFIRMATION NO.
3405GROUP
1646

Use several sheets if necessary

U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	A1	5,194,596	03-16-1993	Tischer, <i>et al.</i>
	A2	5,350,836	09-27-1994	Kopchick, <i>et al.</i>
	A3	5,955,594	09-21-1999	Mishra
	A4	6,416,974 B1	07-09-2002	Holtzman, <i>et al.</i>
	A5	2002/0112251 A1	08-15-2002	McCarthy, <i>et al.</i>
	A6	5,686,601	11-11-1997	Weber
	A7			
	A8			
	A9			
	A10			
	A11			
	A12			
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	A23			
	A24			
	A25			

EXAMINER

DATE CONSIDERED

PTO-1449 REPRODUCED INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION April 12, 2006 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 1855.2058-001		APPLICATION NO. 10/718,332	
	FIRST NAMED INVENTOR Sean A. McCarthy		FILING DATE November 20, 2003	
	EXAMINER Not yet assigned		CONFIRMATION NO. 3405	GROUP 1646

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO	
	B1	WO 99/06427	02-11-1999	Millennium Biotherapeutics, Inc.		
	B2	WO 00/04140	01-27-2000	Human Genome Sciences, Inc.		
	B3	WO 96/01896	01-25-1996	Human Genome Sciences, Inc.		
	B4	EP 0 874 050 A2	10-28-1998	Smithkline Beecham Corporation; Smithkline Beecham PLC; Human Genome Sciences, Inc.		
	B5	WO 98/56804	12-17-1998	Human Genome Sciences, Inc.		
	B6	WO 99/37660	07-29-1999	Iruela-Arispe, L., <i>et al.</i>		
	B7	WO 00/71577 A1	11-30-2000	Human Genome Sciences, Inc.		
	B8	WO 94/01548 A2	01-20-1994	Medical Research Council		
	B9					
	B10					
	B11					
	B12					
	B13					
	B14					
	B15					
	B16					
	B17					

EXAMINER

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	FIRST NAMED INVENTOR Sean A. McCarthy		FILING DATE November 20, 2003	
	EXAMINER Not yet assigned	CONFIRMATION NO. 3405	GROUP 1646	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

C1	Fricker, L.D., <i>et al.</i> , "Identification and Characterization of ProSAAS, a Granin-like Neuroendocrine Peptide Precursor that Inhibits Prohormone Processing," <i>J. Neurosci.</i> , 20(2):639-648 (2000).
C2	GenBank Accession No. AF196971, "Homo sapiens GATA-binding Protein 1 and Histone Deacetylase-like Protein Genes, Complete cds; CRAS pseudogene, Complete Sequence; and Protein Translocase Gene, Partial cds," (1999) [online], [retrieved on 06/21/2005]. Retrieved from the Internet: <URL:http://www.ncbi.nlm.nih.gov>.
C3	Vukicevic, S., <i>et al.</i> , "Induction of Nephrogenic Mesenchyme by Osteogenic Protein 1 (Bone Morphogenetic Protein 7)," <i>Proc. Natl. Acad. Sci. USA</i> , 93:9021-9026 (1996).
C4	GenBank Accession No. G06805, "Human STS WI-8007," (1995) [online], [retrieved on 12/20/2001]. Retrieved from the Internet: <URL:http://www.ncbi.nlm.nih.gov>.
C5	Collignon, J., <i>et al.</i> , "Relationship Between Asymmetric <i>nodal</i> Expression and the Direction of Embryonic Turning," <i>Nature</i> , 381:155-158 (1996).
C6	Taguchi, A., <i>et al.</i> , "Molecular Cloning of Novel Leucine-Rich Repeat Proteins and Their Expression in the Developing Mouse Nervous System," <i>Mol. Brain Res.</i> , 35:31-40 (1996).
C7	GenBank Accession No. AA133346, "zl17a11.l Soares_Pregnant_Uterus_NbHPU Homo sapiens cDNA Clone IMAGE:502172 5', mRNA Sequence," (1997) [online], [retrieved on 05/11/2005]. Retrieved from the Internet: <URL:http://www.ncbi.nlm.nih.gov>.
C8	Kuno, K., <i>et al.</i> , "Molecular Cloning of a Gene Encoding a New Type of Metalloproteinase-disintegrin Family Protein with Thrombospondin Motifs as an Inflammation Associated Gene," <i>J. Biol. Chem.</i> , 272(1):556-562 (1997).
C9	Pan, G., <i>et al.</i> , "The Receptor for the Cytotoxic Ligand TRAIL," <i>Science</i> , 276:111-113 (1997).
C10	Sirotkin, H., <i>et al.</i> , "Identification, Characterization, and Precise Mapping of a Human Gene Encoding a Novel Membrane-Spanning Protein From the 22q11 Region Deleted in Velo-Cardio-Facial Syndrome," <i>Genomics</i> , 42:245-251 (1997).
C11	Sonnenfeld, M., <i>et al.</i> , "The <i>Drosophila tango</i> Gene Encodes a bHLH-PAS Protein that is Orthologous to Mammalian Arnt and Controls CNS Midline and Tracheal Development," <i>Development</i> , 124:4571-4582 (1997).

EXAMINER	DATE CONSIDERED
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PTO-1449 REPRODUCED INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION April 12, 2006 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 1855.2058-001		APPLICATION NO. 10/718,332	
	FIRST NAMED INVENTOR Sean A. McCarthy		FILING DATE November 20, 2003	
	EXAMINER Not yet assigned		CONFIRMATION NO. 3405	GROUP 1646

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

C12	Bradham, D.M., <i>et al.</i> , "Connective Tissue Growth Factor: a Cysteine-rich Mitogen Secreted by Human Vascular Endothelial Cells is Related to the SRC-Induced Immediate Early Gene Product CEF-10," <i>J. Cell Biol.</i> , 114(6):1285-1294 (1991).
C13	Briehl, M.M. and Miesfeld, R.L., "Isolation and Characterization of Transcripts Induced by Androgen Withdrawal and Apoptotic Cell Death in the Rat Ventral Prostate," <i>Mol. Endocrinol.</i> , 5(10):1381-1388 (1991).
C14	Mason, E.D., <i>et al.</i> , "Dorsal Midline Fate in <i>Drosophila</i> Embryos Requires <i>twisted gastrulation</i> , a Gene Encoding a Secreted Protein Related to Human Connective Tissue Growth Factor," <i>Genes Dev.</i> , 8:1489-1501 (1994).
C15	GenBank Accession No. H27128, "y166b06.rl Soares ...," (1995) [online], [retrieved on 12/20/2001]. Retrieved from the Internet: <URL:http://www.ncbi.nlm.nih.gov>.
C16	Campbell, A.M., "General Properties and Applications of Monoclonal Antibodies," in <u>Monoclonal Antibody Technology: the Production and Characterization of Rodent and Human Hybridomas</u> (Elsevier Science Publishers B.V., Amsterdam, Netherlands, pp. 1-32 (1984).
C17	GenPept Accession No. P97857, "Adamts-1 Precursor (A Disintegrin and Metalloproteinase with Thrombospondin Motifs 1) (Adamts-1)," (2000) [online], [retrieved on 6/22/2005]. Retrieved from the Internet: <URL:http://www.ncbi.nlm.nih.gov>.
C18	GenBank Accession No. D61105, "HUM156H09B Clontech human fetal brain polyA+ mRNA (#6535) Homo sapiens cDNA clone GEN-156H09 5', mRNA sequence," (1995) [online], [retrieved on 6/29/2005]. Retrieved from the Internet: <URL:http://www.ncbi.nlm.nih.gov>.
C19	GenBank Accession No. H41372, "yn91c11.21 Soares adult brain N2b5HB55Y Homo sapiens cDNA clone IMAGE: 175796 3' similar to contains TAR1 repetitive element; , mRNA sequence," (1995)[online], [retrieved on 6/29/2005]. Retrieved from the Internet: <URL:http://www.ncbi.nlm.nih.gov>.
C20	"Sequence Revision History: Revision history for P97857," (2006) [online], [retrieved on 3/27/2006]. Retrieved from the Internet: <URL:http://www.ncbi.nlm.nih.gov>.
C21	"UniProtKB/Swiss-Prot entry P97857" (2005) [online], [retrieved on 6/22/2005]. Retrieved from the Internet: <URL:http://www.expasy.org>.

EXAMINER	DATE CONSIDERED
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